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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,066	09/24/2004	Ulrich Abel	12874-00001-US	1371
23416 7590 01/10/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/509,066

Applicant(s)

ABEL ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15, 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims pending 1-10, 15 and 16.

The rejection of claims 11-12 under 35 USC 112 second paragraph has been withdrawn as applicants have cancelled the claims..

The rejection of claims 1-10 under 35 USC 112 second paragraph has been withdrawn as applicants have deleted the term "residue".

The rejection of claims 1-14 (now over claims 1-10, 15 and 16) under 35 USC 112 first paragraph still stands. invention. The claims recites in the definition of the various R variables the heterocyclo and heteroaryls, heterocyloalkyl,, alkylheteroaryl (all group with the hetero encompassed in it) but the specification s do not have any definition of what these group are.

Also in various places the claims recite forming a ring with N, O or S, but there is no definitions as to which groups are encompassed by this, in the specification.

Applicants argue that the terms are disclosed in paragraph 0078 or 0071. hetero aryl is disclosed at paragraph 0082, Alkylheteroaryl is disclosed at paragraph 0071 and 0082.

The specifications *do not have any paragraphs numbers* and it is not clear what the applicants are referring to.

Applicants also argue that there are different agents given through out the specification but have not given the locations. The examiner cannot find any of the agents as claimed. Page 9 just has a statement indicating "Also preferred are the above mentioned drugs in combination with other agents for tumor treatment." But there is no description of what these are.

Thus the rejection still stands.

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The rejection of claims 1-10, 15 and 16 under 35 USC 112 first para scope of enablement.

Also still stands. [The specification do not have any structures in the tables.].

There is no data and guidance that these various diseases such as tumors and or parasites administered in an "effective" amount does in fact treat a tumor or parasites. The specification have some IC70 activity for some 29 compounds, that too it ranges from .0030 to .3000 and is no indication that this does treat tumors or parasites.

Applicants argue with respect to other patents US 4584377, US4673,678, US 5266208 have no working examples either. The examiner will not comment on other documents.

In re Giolito and Hoffman, 188 USPQ 645 (CCPA 1976).

The rejection still stands.

The rejection of claims 1-14(now 1-10, 15 and 16) under 35 USC 103 over US 4584377, US 4673678, US 5166208 and Cyclodextrin solubilization.... Matt Duan et al, Raquel Delgado et al, Kazuto Okimoto et al still stands.

Applicants arguments are that the US documents do not disclose the compounds of the invention and that the Matt Duan et al, Raquel Delgado et al, Kazuto Okimoto et al teaches including cyclodextrin for making drugs more soluble, however it does not teach using the cyclodextrin for the fredericamycin. This may be correct or else it would be a 102 rejection. The Matt Duan et al, Raquel Delgado et al, Kazuto Okimoto et al teaches using cyclodextrin to make drugs more bioavailable. The US patent teaches the frederimycin and way of making them more soluble using polyethylene glycols, sugars etc. Thus the motivation comes from making the compound more bioavailable and thus more effective. Thus at the time of the invention was

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made cyclodextrin was known to make drugs more soluble, thus one of skill in the art would have been motivated to include the cyclodextrin to drugs to increase the solubility.

The rejection still stands.

Applicants have used paragraph numbers, but the specification as sent do not have any paragraph numbers. Thus applicants arguments are not clearly understood.

New Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 14 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending

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Application No. US 2005/0215579 and claims 1-14 of US 2005 /0153997 . Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same fredericamycin derivatives and inclusion compounds or complexes for the same use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-10, 15 and 16 are not allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

R. Desai
1/4/07

R.D.
January 4, 2007